United States Army Medical Materiel Agency

Distribution Operations Center (USAMMA/DOC)

Temperature Sensitive Medical Products (TSMPs)

Cold Chain Management

Overview

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Historical Events

1997 – Secretary of Defense approved Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP)

**Army designated Executive Agent (EA)

1998 – Loss of 200,000 doses of Anthrax Vaccine (AVA).

1998 – USAMMA tasked to perform DoD distribution of AVA

**Created Distribution Operations Center (DOC) to manage DOD AVA Distribution

**Cold Chain Management Principles/Procedures (CCM) were developed

1999 – Military Vaccine Agency (MILVAX) replaced MEDCOM as AVIP policy developer/clinical guidance

USAMMA DOC FUNCTIONS

The Distribution Operations Center (DOC) manages critical vaccines and pharmaceutical products which may or may not require Cold Chain Distribution, to include; the packaging, storage and special handling requirements of the medical material requiring refrigeration; the management of the shipment; and the oversight of the product from initial requesting agency, to end user, in support of DOD personnel and operations.

DOC is also responsible for DOD Medical Materiel Quality Control (MMQC) messages and Army Medical Materiel Information (MMI) messages.

Core Products Overview

- Anthrax Vaccine
- Smallpox Vaccine (ACAM2000)
- Influenza Vaccine
- Adenovirus Vaccine (Type 4 & Type 7)
- Vaccinia Immune Globulin intravenous (VIGIV)
- Investigation New Drug (IND) products
- FMS (Foreign Military Sales)
- Other Temperature Sensitive Medical Products (TSMP's)-(He-Bat, Rabies etc..)
- Other Non-Temperature Sensitive Critical products

Why are we here?

- **The great loss of 1998 – Over 200,000 doses of Anthrax Vaccine was compromised due to freezing.**

- **Sites contribute to thousand of dollars each year in vaccine losses.**

- **Major Factors:**
  - Mechanical Failures- such as alarm system and power outages/supply malfunctions.
  - Human Process Failures- such as poor cold chain management techniques.
  - Failure to follow policies- procedures and local regulations.

Cold Chain Management (CCM) Process and Procedures

- Vaccines are sensitive biological substances that can lose their potency and effectiveness if exposed to heat, extreme cold and/or light

- **Minimize waste/save thousands of tax payers dollars**
  - Prevent vaccine from being compromised
  - Assures vaccine maximum shelf life and suitability for use by minimizing the rate of deterioration
  - Some vaccine are in critically short supply

- The loss of vaccine potency **CANNOT** be reversed

- Assures leadership, service members and DoD beneficiaries that vaccine/products are safe to use and fully effective .

Cold Chain Management (CCM) Process and Procedures

US Pharmacopeia (USP) Temperature Standards

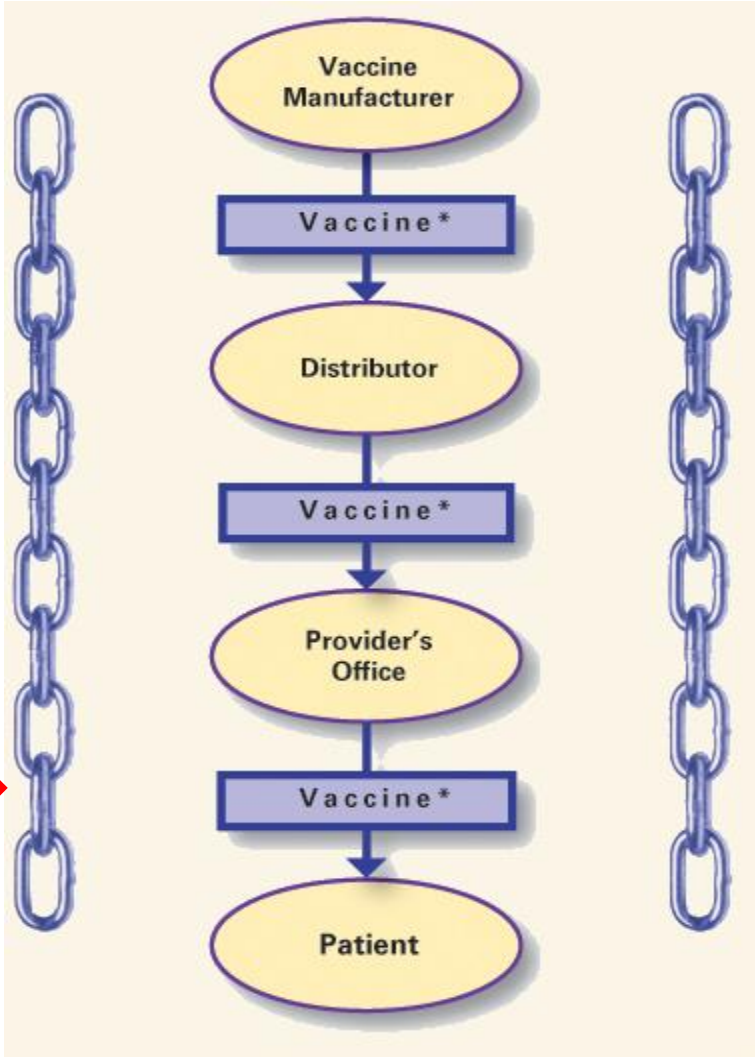
- Refrigerated Storage - Thermostatically controlled from 2°C to 8°C; approximately 35°F to 46°F
- Frozen Storage - Thermostatically controlled from -20°C to -10°C; approximately -4°F to 14°F
- Room Temperature- Thermostatically controlled from 20°C to 25°C; approximately 68°F to 77°F

What is Cold Chain Management

Cold chain begins with the cold Storage unit at the vaccine manufacturing plant

Extends through the transfer of vaccine To the distributor

The Chain is most Compromised at the point of 'Provider to Patient'



TSMP Coordinator

Responsible for:

- Developing a Routine Vaccine Storage and Handling plan, kept in a visible location near all vaccine storage units.
  - Current contact information for the primary and back-up vaccine coordinators
  - Pharmacy, logistics, local Regional Analyst, USAMMA
  - Vaccine manufacturers, the medical equipment repair office
  - Storage unit alarm company
  - Written emergency plan – natural disasters, power outages etc.
  - Temporary placement of vaccine in a working refrigerator

TSMP Storage & Handling Equipment

Selecting the Proper Storage Unit

- Should be large enough to store the year's largest inventory in the middle shelves without crowding.
- Stand-alone refrigerators and freezers are recommended
- Combination refrigerator/frost-free freezer for home use is acceptable if there are separate compartments, external doors and thermometer controls
- **NOT RECOMMENDED** – Dormitory style refrigerators for 'permanent' vaccine storage (clinic's single-day supply) the freezer section should never be used
- Well-ventilated room, with adequate space around the sides
- Good air circulation – for proper heat exchange and cooling functions

TSMP Storage & Handling Equipment

Thermometers

Accurate thermometer readings are essential to determine whether vaccine are maintained a the required temperature

- Storage units should have a National Institute of Standards and Technology (NIST) certified and calibrated thermometer – in each compartment (refrigerator/freezer)
- Continuous graphic recorder thermometer, monitors ranges and durations is recommended
- Uncertified liquid (mercury or alcohol) thermometers and dial-type are not authorized
- Thermometers should be placed in the center of the compartment away from coils, walls, floor, and fan

Monitoring & Recording Temperatures

- Manually confirm the temperature of ALL vaccine storage units a minimum of **TWO** times a day – once at the beginning of the workday and once at the end of the workday

- Applies regardless of whether or not there is a 24-hour/7-day temperature alarm system, chart recorder thermometer, or a digital data logger

THERE IS NO SUBSTITUTE FOR MANUALLY CHECKING/ DOCUMENTING THE TEMPERATURE TWICE A DAY

- Document the date, time, and temperature on a vaccine log

- Pay special attention to any trend in deviation of temperature, this could indicate a possible future mechanical malfunction or power outage of the storage unit

Temperature Monitoring

Temperature Log for Vaccines (Celsius)

Month/Year:_____

Completing the temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature readings, and you initials. Once the month has ended, save each month's form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents unacceptable temperature range. Follow these steps: 1. Label vaccine as "potentially compromised." 2. Move vaccine to functioning storage area as quickly as possible. 3. Call *USAMMA immediately to determine if potency of vaccines has been affected. 4. Call your Regional Analyst for further assistance.

Day of the month	17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Staff Initials																														
Room Temp.																														
Exact Time																														
°C Temp	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Too warm* ≥11°	Take immediate action if temperature is in shaded section*																													
10°																														
9°																														
Refrigerator temperature 8°																														
7°																														
6°																														
5°																														
Aim for 4° 4°																														
3°																														
2°																														
Too cold* 1°	Take immediate action if temperature is in shaded section*																													
0°																														
≤1°																														
Too warm* ≥12°	Take immediate action if temperature is in shaded section*																													
Freezer temp -13°																														
-14°																														
-15°																														
-16°																														
≤-17°																														

***USAMMA Emergency Telephone Numbers:** Phone 301-619-4318/1197/4198, DSN (343), After Hours: 301-676-1184/0857, E-mail: USAMMADOC@amedd.army.mil

Adapted by the Military Vaccine (MILVAX) Agency courtesy of the Immunization Action Coalition.

Protecting the Power Supply

Storage units should be plugged directly into wall outlets; multi-strip outlets or extension cords should **NOT BE USED**

- Plugs should be secured to the electrical outlet to prevent the unit from accidentally being unplugged or turned off
- The use of a safety-lock plug
- Outlet cover or a cover with a cage/prevents accidental disconnection
- Highly visible stickers by the electrical outlets to make sure that the the unit is not unplugged – vacuum cleaner etc……

Multilingual stickers are on the Centers for Disease (CDC) website to alert non-English speaking housekeeping or clinic staff

Safe Guarding Alarming Devices

- Alarms should be monitored electronically and physically 24 hours a day, seven days a week – **NO EXCEPTIONS**

- At the time of a power failure the system should

  - **IMMEDIATELY** notify an accountable person

  - The system should be able to provide continuous temperature monitoring in order to verify that the integrity of the vaccine stayed within the proper temperature during storage.

- **Monthly** testing of the entire system insures POCs/phone numbers are accurate – records kept for three years

- Backup generators/should be capable to run for 72 hours

TSMP Inventory Management

- Identify and be accurate when ordering a supply of vaccines
- Disposal of expired vaccine leads to costly waste of taxpayers money
- Vaccines are expensive and the cost is continuously rising
- **DO NOT OVERSTOCK** vaccine, if a compromise occurs there is a risk of losing a large amount of vaccine
- Monitor vaccine usage and rotate stock

Receiving TSMP Shipments

- Upon delivery – open the package as soon as possible
  - Verify that the amount received matches the packing slip
  - Check the expiration dates on the vaccines (using the shortest-dated vaccine first)
  - Refrigerate vaccines in their original box – removing exposes the vaccine to room temperature and light
  - Immediately place vaccine in the proper storage container within the refrigerator/freezer

Anthrax Vaccine/Smallpox Vaccine/Adeno Virus Vaccine

Once the box is delivered, call USAMMA DOC immediately, a case manager Will instruct you to read the TempTale, place it in the appropriate return envelope, pending the digital reading from the TempTale will determine if the vaccine is ‘verbally released’ or not

Safe Guarding TSMPs

- Store vaccines on the middle shelves **NEVER** store vaccines on the doors/vegetable bins

- Proper air circulation is imperative – leave adequate space between packages to maintain proper air flow

- Proper storage of vials within the storage unit
  - eliminates the wrong type of vaccine being administered
  - monthly inventory more efficient
  - expiration and tracking of the vaccine easier

- Store each vaccine in its own labeled section

- Bins, baskets with slotted sides should also be labeled

- Verify the type of vaccine and expiration date before administrating

TSMP Transport Procedures

Protecting Vaccines at Off-Site Immunizations Sessions

- Pack only the expected amount that will be used during the immunization session

- Minimize the number of times the container is opened

- Transport vaccine in an approved/validated insulated container **ONLY**.
  - No brown paper bags
  - No uncertified Styrofoam coolers

- Vaccines taken to an off-site clinic
  - fill out an issue receipt/number/type of vials taken
  - vaccine must be maintained at 2-8

- Returning vaccine
  - document the number/type of vials returned
  - verify the vaccine was maintained at 2-8

Equipment Used to Support Cold Chain Distribution

CCM Equipment - Temperature Monitors

The TempTale multiple use temperature monitor system provides complete time and temperature history on all of our temperature sensitive product shipments. Data collected is used to validate that our products have preserved their integrity during distribution from the manufacturer to the end user. The TempTale temperature monitor is manufactured by Sensitech, Inc. This device can be set to read every ten (10) minutes for approximately two (2) weeks and record 2,000 data points

CCM Equipment
Insulated Shipping Container

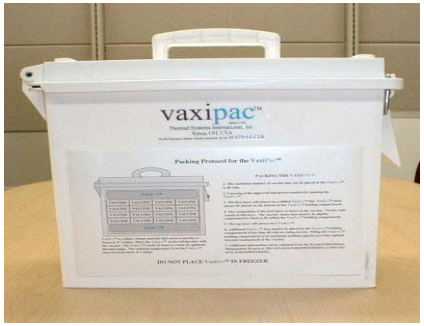
• The Insulated shipping container (Endurotherm box) is used to ensure the cold chain distribution process is not broken during transporting TSMP's. There are four different sizes: small, medium, large and extra large. The boxes have gone through various testing protocols and they can maintain the required temperature guarantee for 3 days and depending upon environment up to 7 days.

VaxiPac (VX1L)/Shipping Container

PERFORMANCE OF ACUTEMP PXC (+7°C)

• **AcuTemp PXC (+7°C) is a safe replacement for ice to keep vaccines and other** temperature sensitive goods cold in the **AcuTemp PX1L without accidental freezing.**
• Used according to the instructions, the **AcuTemp PX1L system will maintain** vaccines/products between 2-8°C (35 – 46°F) for more than 20 hours at an ambient temperature of 24°C (75°F).

• As the ambient temperature increases, the hold time will decrease:
a. 15 hours @ 30°C (86°F)
b. 12 hours @ 37°C (99°F)
c. 9 hours @ 48°C (118°F)



PXC (+7°C) must be chilled at 3°C (±1°C) for 24 hours.

A maximum of 24 vials can be placed in the VaxiPac (a full layer consists of 12 vials).

When placing PXCs in the PX1L, be sure to keep the pull-tab“UP” so that the pack can be removed easily

AcuTemp AX27L Mobile Refrigerator/Freezer

The AcuTemp AX27L mobile refrigerator/freezer addresses the need for a small, non-CFC refrigeration unit that offers energy efficiency, precision temperature control and easy portability. With a 27 liter payload capacity and two temperature set-points (+4°C or -22°C) to accommodate payloads requiring refrigeration or freezing, this mobile thermal management unit is designed to safely transport and store temperature-sensitive vaccines, drugs, specimens and other bio-medical materials

Power Sources
Grid power (standard): 115 VAC or 230 VAC, 50-60 Hz
Battery (standard): Two 21 amp. hr. gel cell batteries
Car lighter outlet (available): 12 VDC

This versatile cold chain solution is capable of operating for up to five days on battery power only, making it perfect for global distribution of small, temperature-sensitive loads

Payload Volume: 27 liters (1 ft3

Payload Dimensions (H x W x L): 26.7 cm x 27.3 cm x 37.5 cm (10.5 in x 10.75 in x 14.75 in)

Tare Weight: 52 kg (114.4 lb)

Responding to TSMP Storage and Handling Problems

Potentially Compromised Vaccine Procedures

- Ensure that the vaccines are placed in a working refrigerator
- Label the vaccine with the words **'DO NOT USE'**
- **Do not** destroy the vaccine
- Emergency TSMP Retrieval and Storage Plan Worksheet
- Contact USAMMA/DOC as well as your MILVAX Regional Analyst (RA) and stand-by for further instructions
- Prepare an Executive Summary (EXSUM)

Emergency TSMP Retrieval and Storage Plan Worksheet

- Vaccine Coordinators – Telephone (Home and Cell)
- Emergency Staff Contact List – Telephone (home and Cell)
- Refrigerator Repair technician, Dry Ice Vendor, Electric Power Company, Temperature Alarm/Generator Repair Company(s)
- Alternate Vaccine Storage Facility(s)
  - Location, Contact Person, Address, Telephone Number
- Emergency Resources Contact List
  - USAMMA/DOC – 24 hour Emergency Line (301) 676-1184/0857
  - Defense Logistics Agency – (215) 737-6658 - (215) 284-6586
  - Milvax Regional Analyst (RA)

How to Prepare an Executive Summary **(EXSUM)**

- Detailed explanation of the circumstances surrounding the potential loss of vaccine potency.
- Location in which the vaccine was discovered
- What was the temperature of the location in which the vaccine was discovered
- List of lot number(s) affected along with expiration dates
- Number of unopened vials involved
- Time & temperature of your last recorded temperature check
- Location of the vaccines at the present time
- Detailed explanation of corrective action(s) to preclude future loss of vaccine
- All points of contact POC(s) information to include name(s), email address and phone

TSMP's DISPOSAL

- DoD activities are responsible for disposal of compromised or expired vaccine
- Destruction memorandum should be routed up the chain of command for review and endorsement before faxing to USAMMA/DOC

- **Methods of Destruction:**

Vaccine vials can be destroyed using the local hospital/clinics disposal procedures for all biohazard/hazard materials

- Can be disposed using returns program when applicable

- Disposition instructions available: http://www.usamma.army.mil/assets/docs/Vaccine_Disposition.pdf

- Destruction Codes can be found on the USACHPPM website: http://phc.amedd.army.mil/topics/envirohealth/hmw/Pages/DisposalGuidance.aspx

USAMMA Website/Cold Chain Links

www.usamma.army.mil

http://www.usamma.army.mil/homepage.cfm

http://www.usamma.army.mil/products.cfm

http://www.usamma.army.mil/cold_chain_management.cfm

Cold Chain References/Guides

U.S. Army Medical Materiel Agency (USAMMA)/Distribution Operations Center (DOC). Available at http://www.usamma.army.mil/cold_chain_management.cfm

Centers for Disease Control and Prevention. General Recommendations of Immunizations. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; Vol. 60 (No. 2).

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed. Washington DC: Public Health Foundation, 2011; 61-74.

Centers for Disease Control and Prevention (CDC). Notice to Readers: Guidelines for Maintaining and Managing the Vaccine Cold Chain. Recommendations of the Advisory Committee on Immunization Practices. MMWR 2003; 52(42); 1023-1025.

Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit. Available at http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/shipments.pdf

Department of the Army, MEDCOM Memorandum, "Safeguarding Temperature Sensitive Medical Products (TSMP)," dated 05 March 2010. Available at http://www.usamma.army.mil/assets/docs/SAFEGUARDING%20TSMP.PDF

SB-8-75-11, Department of the Army Medical Department Supply Bulletin. Section 3-65: Temperature Sensitive Medical Products (TSMP) Storage and Handling (pg 62) Available at https://www.vaccines.mil/storageandhandling

The Joint Commission, Standards Frequently Asked Question Details. Available at http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?